



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,842	12/10/2001	Reena Rao	11378.36US01	1838
23552	7590	08/24/2006	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			COTTON, ABIGAIL MANDA	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



### **DETAILED ACTION**

This office action is in response to the amendment and remarks submitted on July 11, 2006. Claims 1-9 and 20 are pending in the application and are being examined on the merits herein.

Applicant's arguments regarding the rejection of the claims over the article by Kailmal et al. for adding new matter have been fully considered but they are not persuasive. Accordingly, this rejection is being maintained.

Applicant's arguments and amendments intended to address the rejection of the claims under 35 U.S.C. 112, first paragraph, as adding new matter, have been fully considered but they are not persuasive. Accordingly, this rejection is being maintained.

Furthermore, Applicant's amendments to the claims have necessitated a new rejection of claim 9 under 35 U.S.C. 112, second paragraph, as set forth below.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

In particular claim 1, from which claim 9 depends, recites that the interesterified oil comprises 46 mol % of omega 6 polyunsaturated fatty acids. However, claim 9 recites that the "level" of the polyunsaturated fatty acids in the interesterified oil is 45.5%. Thus, the metes and bounds of claim 9 cannot be determined, as it is unclear whether the amount of the omega 6 polyunsaturated fatty acids is intended to be 46 mol %, or 45.5 mol%, or whether perhaps the "level" of the fatty acids as recited in claim 9 is intended to refer to some measure other than the mol percent that is recited in claim 1. Accordingly, as the metes and bounds of the claim cannot be determined, claim 9 is indefinite under 35 U.S.C. 112, second paragraph. Appropriate correction and/or clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

Art Unit: 1617

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, claim 1 recites the interesterified oil comprising 6 mol % of omega 6 polyunsaturated fatty acids” in general, which is not supported by the specification as originally filed. While the specification provides support for 46 mol % of the specific omega polyunsaturated fatty acid that is linoleic acid (see Table I), the specification does not teach providing the recited mol % for omega 6 polyunsaturated fatty acids in general. Thus, the amended claims are deemed to add new matter into the specification. Claims 2-9 and 20 are rejected under 35 U.S.C. 112, first paragraph, as depending from a claim having new matter.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 and 20 are rejected under 35 U.S.C. 103(a) as being obvious over the article entitled “Modification of Vegetable Oils by Lipase Catalyzed Interesterification” by Kaimal et al (of record.)

Kaimal et al. teaches lipase catalyzed interesterification as a means to modify the fatty acid and glyceride content of common vegetable oils to alleviate drawbacks of these oils (see abstract, in particular.) With regards to coconut oil Kaimal et al. teaches that coconut oil is a saturated fat with lauric acid constituting one of the major fatty acids (see paragraph bridging pages 2-3, in particular.) Kaimal et al. teaches that coconut oil is low in linoleic acid, an essential fatty acid (omega 6 polyunsaturated fatty acid), and thus teaches that it is desirable to remove the C-16 and C-18 saturated acids and incorporate linoleic acid in sufficient amounts to provide essential fatty acid requirements and nutritional quality, as well as to provide medium chain fatty acids that are better absorbed and metabolized (see paragraph bridging page 2-3, in particular.) To this end, Kaimal et al. teaches that lipase catalyzed interesterification can be used to modify coconut oil by reducing the higher saturated acids with simultaneous incorporation of medium chain fatty acids and linoleic acid (see page 3, left hand columns first through fifth full paragraphs, in particular.)

Kaimal et al. provide examples of the interesterification of coconut oil to improve the nutritional quality of the oil (see paragraph bridging page 7-8 and page 8, in particular.) Kaimal et al. teaches that medium chain fatty acids such as capric and myristic acid are introduced into the coconut oil to reduce the content of higher saturated acids in the oil (see paragraph bridging pages 7-8 and first full paragraph on page 8, in particular.) Kaimal also teaches that in an attempt to incorporate linoleic acid into coconut oil, the coconut oil was interesterified with a mixture of fatty acids including

Art Unit: 1617

the capric and myristic acids, as well as safflower oil (see page 8, paragraph bridging right and left hand columns, in particular.) Table 17 lists the contents of the resulting interesterified coconut oil, showing an increased linoleic acid (18:2) content over the non-interesterified oil. Kaimal et al. teaches that the coconut oil product may be suitable as a dietary oil for patients with impaired lipid metabolism and for patients under coronary care (see page 8, first full paragraph in left hand column, in particular.)

Accordingly, Kaimal et al. teaches an interesterified coconut oil comprising fatty acids obtained from triglycerides of safflower oil, namely linoleic acid (an omega 5 polyunsaturated fatty acid), and further teaches that the interesterified oil comprises lauric acid because Kaimal et al. teaches that lauric acid is a major fatty acid constituent of coconut oil (see paragraph bridging pages 2-3, in particular.)

Kaimal et al. does not specifically teach the interesterified coconut oil comprising the recited mol % of omega 6 polyunsaturated fatty acids and lauric acid. However, Kaimal et al. clearly teaches that fatty acids such as linoleic acid (via interesterification with safflower oil), capric acid and myristic acid can be incorporated into the oil to provide nutritional benefit and can replace the existing fatty acids, especially long chain saturated acids (see paragraph bridging pages 2-3 and pages 7-8 in particular.) Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amounts and ratios of safflower oil and/or other fatty acids (such as even linoleic acid) that are combined

with the coconut oil in the interesterifying reaction, according to the guidance provided by Kaimal et al, to provide an interesterified coconut oil having desired nutritional properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

It is respectfully pointed out that instant claims 1-9 and 20 are product-by-process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113. In the instant case, the claimed product is obvious from the prior art, because the prior art product comprises interesterified coconut oil having fatty acids that are obtained from the triglycerides of safflower oil, such as linoleic acid. The product thus obtained by the lipase enzyme is deemed to be equivalent to an interesterified coconut oil wherein the fatty acids are obtained from the hydrolysis of triglycerides of safflower oil, as claimed.

Furthermore, it is noted that claim 1 as written reads on interesterifying coconut oil with any of the free fatty acids that are obtained from the hydrolysis of triglycerides of safflower oil, which reads on the interesterification of coconut oil with linoleic acid, a



fatty acid that can inherently be obtained in free form from the hydrolysis of triglycerides of safflower oil. Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to incorporate linoleic acid into the coconut oil, in an amount and percent by mol as desired, to provide an interesterified coconut oil that is an obvious variant of the product-by-process recited in claim 1. One of ordinary skill in the art would furthermore find it obvious to vary the amount and percent by mol of the linoleic acid incorporated into the coconut oil, for example to arrive at the percent by mol recited in claim 1, with the expectation of providing an interesterified coconut oil having beneficial nutritional properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Accordingly, claim 1 is obvious over the teachings of Kaimal et al.

While it is not being specifically relied on for the present rejection, it is noted that Applicants teach on page 6 of the instant Specification that the method for the hydrolysis of triglycerides of vegetable oils is known in the art.

Claims 2-3 are directed to compositions wherein the lauric acid provides quick energy for critically ill patients, and is nutritionally beneficial in being hypocholesterolemic and hypotriglyceridemic. It is noted that Kaimal et al. teaches that

the interesterified coconut oil can be used as a dietary oil for patients with impaired lipid metabolism and for patients under coronary care (see page 8, right hand column, first full paragraph, in particular.) Furthermore, as the teachings of Kaimal et al. renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely the quick energy for critically ill patients and nutritional benefits, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

Claims 4 and 6 are directed to compositions wherein the interesterified coconut oil reduces total cholesterol levels in serum by a recited amount, and increases eicosanoid production in immune compromised patients. It is noted that Kaimal et al. teaches that the interesterified coconut oil can be used as a dietary oil for patients with impaired lipid metabolism and for patients under coronary care (see page 8, right hand column, first full paragraph, in particular.) Furthermore, as the teachings of Kaimal et al. renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely the reduction in serum cholesterol level and increased eicosanoid production, are

inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

Regarding claim 5, Kaimal does not specifically teach that a recovery percentage of the interesterified coconut oil, and thus does not specifically teach a recovery percentage that is in the range of 88-92%, as recited in the claim. However, Kaimal et al. does teach several methods of interesterification of the oils, including by batch stirred reaction and packed-bed continuous reaction (see page 3, right hand column, in particular.) Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to select among the methods taught by Kaimal to obtain a desired recovery percentage of the interesterified coconut oil. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 8, Kaimal et al. teaches an interesterified coconut oil having safflower oil fatty acids and triaglycerols of coconut oil, as discussed above.

Claim 7 is directed to a composition wherein the interesterified coconut oil has a melting point as claimed and remains a liquid without phase separation. It is noted that as the teachings of Kaimal et al. renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely the melting point and phase separation properties, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

Regarding claim 9, it is noted that Kaimal teaches an interesterified coconut oil wherein the starting oil is simply coconut oil, and thus has the n-6 PUFA levels that are as claimed or at least are close to those as claimed, and furthermore teaches that linoleic acid can be incorporated into the coconut oil by interesterification, for example via safflower oil, as discussed above. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of linoleic acid and/or safflower oil provided for transesterification with the coconut oil, according to the guidance provided by Kaimal et al, to provide an interesterified coconut oil having desired nutritional properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is

Art Unit: 1617

not inventive to discover the optimum or workable ranges by routine experimentation."

In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 20, it is noted that Kaimal et al. teaches that capric and myristic fatty acid can be interesterified into the coconut oil (see pages 7-8, in particular), as discussed above. Kaimal et al. also teaches that non-interesterified coconut oil itself has a quantity of capric acid fatty acids (10:0) and myristic fatty acids (14:0) (see Table 17, in particular.) Kaimal et al. further teaches that long chain saturate fatty acids such as palmitic acid and stearic acid, can be removed from the fat and replaced with medium chain length fatty acids during the interesterification process (see paragraph bridging pages 2-3, in particular), and teaches the quantities of palmitic acid (16:0) and stearic acid (18:0) present in the non-interesterified coconut oil (see Table 17, in particular.) Kaimal et al. also teaches that oleic acid (18:1) is present in the non-interesterified coconut oil (see Table 17, in particular), and teaches that oleic acid can be incorporated via interesterification into oils to reduce the content of unwanted fatty acids (see page 4, in particular.) Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the fatty acids provided in the interesterified coconut oil, for example by interesterifying with the fatty acids or replacing the fatty acids in the oil with other fatty acids via interesterification, according to the guidance provided by Kaimal et al, to provide an interesterified oil having desired nutritional properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not

inventive to discover the optimum or workable ranges by routine experimentation." In *re* Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

### ***Response to Arguments***

Applicant's arguments filed July 11, 2006 have been fully considered but they are not persuasive.

Applicants argue that the claims have been amended to overcome the rejection under 35 U.S.C. 112, first paragraph, by removing the term "about" from the claims. However, the Examiner notes that the claims remain rejected because the specification does not teach that the mol % as recited is generally applicable for all polyunsaturated omega 6 fatty acids other than linoleic acid, as discussed above.

Applicants argue that the Kaimal et al. does not render the composition obvious because Kaimal et al. does not teach the specific mol %'s of the components as claimed. However, as discussed above, Kaimal et al. teaches the desirability of incorporating linoleic acid into the coconut oil via interesterification to provide nutritional benefits, and furthermore exemplifies providing the linoleic acid via interesterification with safflower oil. Accordingly, even though Kaimal et al. does not teach the specific mol percentages of linoleic acid as claimed, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or

optimize the amount of linoleic acid provided in the interesterified coconut oil, according to the guidance provided by Kaimal et al, to provide an interesterified coconut oil having desired nutritional properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

It is furthermore noted that Kaimal et al. teaches that the fatty acids in coconut oil can be selectively provided or removed according to the desired nutritional and/or cooking benefits, and teaches caprylic, capric, and oleic acid as acids that are present in non-interesterified coconut oil, and which can optionally be added with fatty acids such as linoleic acid into the coconut oil via interesterification. Accordingly, even though Kaimal et al. does not teach the specific mol percentages of components as claimed, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the components provided in the interesterified coconut oil, according to the guidance provided by Kaimal et al, to provide an interesterified coconut oil having desired nutritional and/or cooking properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Applicants furthermore argue that Kaimal et al. follows a different method to generate the product than that claimed, namely the lipase-catalyzed interesterification of coconut oil with safflower oil, whereas the instant claims recite interesterification with free fatty acids obtained from hydrolysis of triglycerides. However, Applicants are respectfully reminded that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113. In the instant case, the product-by-process as claimed is obvious over the product of Kaimal et al, as discussed above.

Applicants furthermore argue that Kaimal et al. does not give clear cut evidence that the observed changes are due to lipase catalyzed modification, as opposed to a result of mere dilution with safflower oil to create a blended oil. The Examiner respectfully points out that Kaimal et al. specifically teaches removing C-16 and C-18 saturated acids and incorporating linoleic acid into the fat (see paragraph bridging pages 2-3) and teaches that incorporation of that linoleic acid into the coconut oil was achieved with interesterification of the coconut oil with fatty acids including capric and myristic acid, as well as safflower oil (see page 8, in particular), of which ingredients only safflower oil is a source of linoleic acid. Kaimal et al. further teaches the resulting



linoleic acid content of the interesterified coconut oil (see Table 17, in particular.)

Accordingly, Kaimal et al. clearly teaches that linoleic acid from the safflower oil is being interesterified into the coconut oil, and does not teach that the safflower oil and coconut oil are merely being blended, as asserted by Applicants. Kaimal et al. further teaches the desirability of linoleic acid itself to provide the desired nutritional value (see paragraph bridging pages 2-3, in particular), and teaches that free fatty acids can be incorporated into the oils, thus it is considered that the method of Kaimal et al. could be used to incorporate linoleic acid from sources other than safflower oil, such as free linoleic acid, as in the case of the capric acid and myristic acid as provided by Kaimal et al.

Applicants also argue that the instant composition has "surprisingly higher" amounts of linoleic acid in comparison to Kaimal et al. While Kaimal et al. does not teach the specifically claimed amount of the omega 6 PUFA, Kaimal et al. does teach that it is advantageous to provide linoleic acid into an interesterified oil, and also teaches methods of achieving the interesterification of linoleic acid into an oil, and thus as discussed above, it is considered that one of ordinary skill in the art would have found it obvious to vary and/or optimize the amount of linoleic acid interesterified into the oil, and thus to arrive at the amount of omega 6 PUFA as recited in the claim. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.) Thus, the higher

incorporation of omega 6 PUFA as claimed is not considered to be "surprising" over the teachings of Kaimal et al.

Applicants also argue that Kaimal et al. teaches away from the amount of omega 6 PUFA as claimed by teaching that "since the recommended maximum daily intake of linoleic acid is only 10% of the total calorie intake, a product with just enough linoleic acid content to satisfy the essential fatty acid requirement with a coconut oil base would yield a product of high stability and good nutritive value" (see page 8, first column), and thus Applicants assert that Kaimal et al. teaches away from providing more than 10% of the linoleic acid. The Examiner notes that Kaimal is referring to 10% of the caloric intake, and not 10 mol % of the product. Furthermore, this teaching of Kaimal et al. is not considered to constitute a teaching away from providing higher amounts of linoleic acid, as Kaimal et al. merely teaches that the amount of linoleic acid provided can be selected in relation to the recommended maximum daily intake of the linoleic acid.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER